

whether a chemical can modulate expression of the human ABC gene;

- IV. Claim 44, drawn to a method of treating atherosclerosis;
- V. Claims 46-47, drawn to a transgenic non-human mammal comprising an ABC promoter having the nucleotide sequence set forth in Seq Id No:1;
- VI. Claim 48, drawn to an unknown compound that modifies expression of the ABC gene; and
- VII. Claim 49, drawn to an isolated ABC gene.

The Examiner alleged that the inventions of Groups I, V, VI and VII are unrelated, stating inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case the Examiner alleged that the products of Group I, V, VI, and VII have different modes of operation, different functions, and different effects, the products of Groups I, V, VI and VII have different chemical structures and may be used in materially different methods. For example, the Examiner alleged that the nucleotide sequence of Group I may be used as a probe in a hybridization assay, the transgenic mammal of Group V may be used as a model for disease, the unknown compound of Group VI may be used to modulate expression of the ABC gene, and the ABC gene of Group VII may be used to transform somatic cells *in vitro*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that require a separate search, restriction for examination purposes as indicated is proper, and the Examiner is requiring the applicants to elect an invention on which further prosecution on

the merits is to proceed.

The Examiner further alleged that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups II, III, and IV because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products.

The Examiner further alleged that the products of Inventions I, V, VI and VII and the methods of Inventions II, III, and IV are unrelated, stating that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case the Examiner alleged that the products of Inventions I, V, VI, and VII and the methods of Inventions II, III, and IV have different functions, different modes of operation, and different effects, and the methods of inventions II, III, and IV may use materially different products which have different chemical structures than the products of Inventions I, V, VI and VII. The Examiner alleged that the products of Inventions I, V, VI, and VII may be used in methods, other than the methods of Inventions II, III,, and IV, having different method steps and requiring materially different products. The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter that would require a different search, restriction for examination purposes as indicated is proper.

In response, applicants hereby elect, with traverse, Group I (i.e. Claims 1-14, and 49) for examination in this application.

However, applicants respectfully traverse the Examiner's Restriction Requirement in its entirety, and particularly with respect to the restriction of claims 15-25 (Group II) from claims 1-14 (Group I).

The separation of claims 15-25 from claims 1-14 is contrary to 37 C.F.R. §1.141, and M.P.E.P. §§ 806.05(h) and 806.05(i) (7<sup>th</sup> Ed.), which requires product claims (e.g. claims 1-14) and process of using claims (e.g. claims 15-25) to be examined in the same application, unless the process of using can be practiced with another materially different product. However, the process claims (15-25) depend on the product claims. Therefore, it is clearly not possible for the process of using to be practiced with a product different from the product claimed in claims 1-14.

Accordingly, applicant respectfully submits that dependent claims 15-25 should be examined together with product claims 1-14 and 49.

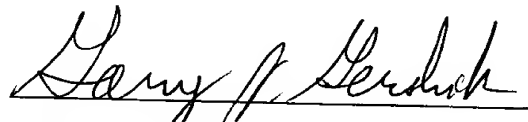
Moreover, the restriction of claims 1-14 from 15-25 is also contrary to the most basic criteria for restriction, as set forth in M.P.E.P. §803. Specifically, M.P.E.P. §803 requires that the "inventions must be independent" and that there "must be a serious burden on the examiner if restriction is not required". However, claims 15-25 are clearly dependent on claims 1-14, which makes the burden of examining claims 15-25 insignificant after the examination of claims 1-14 is completed.

Accordingly, applicant respectfully requests the Examiner to reconsider and withdraw the restriction requirement, and at minimum examine claims 1-25 and 49 in this application.

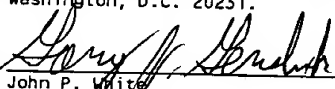
Applicants: Alan R. Tall  
U.S. Serial No.: 09/560,372  
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Page: 5

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
 John P. White Reg. No. 28,678 Gary J. Gershik Reg. No. 39,992	<u>10/12/01</u> Date